CARDIOLINE®

ar600

user manual

CE 0470

English

This User Manual is prepared with the objective of providing the user with all of the information necessary to obtain the best use of the **CARDIOLINE® ar600**. Together with a description of the equipment's functions the following documentation will be found:

- Certificate of Guarantee

General information

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1 Introduction

ar600 embodies the features of reliability, modularity, versatility and upgradability that characterize the latest generation of **CARDIOLINE®** electrocardiographs.

ar600 is a portable electrocardiograph with dual power supply, (mains and rechargeable internal batteries), which in the basic configuration allows:

- ✓ recording of an ECG in either automatic or manual mode;
- ✓ printing the ECG on 60 mm single channel format paper using a high-resolution thermal print;
- ✓ storing the most recent ECG recording in automatic mode and printing additional copies of the ECG as required.

Thanks to the flexibility of the software used and to the infrared interface, the **ar600** can be adapted at any given moment to suit your individual requirements. The range of "*options*" offered is particularly generous and there are no restrictions or constraints, as the selection can be made either at the moment of purchase or later on at your clinic or surgery without having to interrupt day-to-day activity.

In just a few minutes your **ar600** can be equipped with:

- "multi-channel option": for printing the ECG signal in 1, 2 and 3 channel format;
- "ECG measurement option": automatic ECG parameter measurement program;
- PC archive option: Archival storage of the ECG in a personal computer running the CARDIOLINE® software for the ECG computerised management .The data upload to the PC is made by use of the wireless "IR" interface; no direct connection to the PC is required.
- PC ECG option: real time display of the 12 ECG leads on a personal computer screen endowed with CARDIOLINE® software for the ECG computerised management. The software can offer an optional module for automatic interpretation of the ECG signal.

CONGRATULATIONS ON YOUR PURCHASE. Your new computerised electrocardiograph CARDIOLINE® has been designed and built in compliance with the applicable regulations in force at the time when et medical devices SpA, Cavareno (Trento) - ITALY drew up this manual. et medical devices operates in accordance with the requirements for quality management systems defined by EN ISO 9001: 2000 and EN ISO 13485: 2003 standards. The system is covered by a Nemko Certification AS (Cert. N. 800278). Your new electrocardiograph has also been built in compliance with the Medical Device Directive 93/42/EEC and is therefore marked by the relevant CE0470 mark.

1.1 How to read the manual

In order to ensure the ® **ar600** is operated in a safe and correct manner, and to appreciate its ease of use and high reliability **the user instructions must be read carefully**.

This documentation describes the functions of your electrocardiograph including those provided by all the possible "options" available. It is therefore possible that some of the functions described may not be present in the model you have purchased. For details of the options, consult the "firmware configuration" chart which accompanies each individual appliance.

☑ This symbol allows you to identify the functions not provided on all models, which must be requested specifically at the time of purchase.

This symbol allows you to identify the functional, behavioral and operational aspects that may be programmed by the type of configuration selected during the step of *"Installation and initial preparation: setup of the electrocardiograph"*.

When a given key is depicted in the body of a sentence or a paragraph, *press* the corresponding key on the appliance to perform the action.

The structure of this manual allows you to approach the use of the electrocardiograph according to your own level of experience. If you are already familiar with **CARDIOLINE®** equipment, the initial fast-track part of each paragraph will allow you to begin working immediately. If you continue reading the paragraph, however, you will see that the individual aspects of the operation are discussed in more detail.

The manual gives detailed information on the use of the model **ar600** for typical ECG procedures, and an introduction to the use of particular functionalities involving interaction with software and a Personal Computer. For instructions on the use of the software applications for Personal Computer, consult the special online guides.

The quick guide to the electrocardiograph (to obtain the printout) sums up the operations linked to the single commands presented in the manual.

Further information and clarifications can be requested directly from:

***CARDIOLINE®** - Product Support*

Strada Rivoltana Nuova, 53, I - 20060 Vignate (MI) ITALIA

e-mail: et.service@etmed.biz

tel. +39 02 95 05 181 fax: +39 02 95 66 013

1.2 Information and recommendations related to safe use

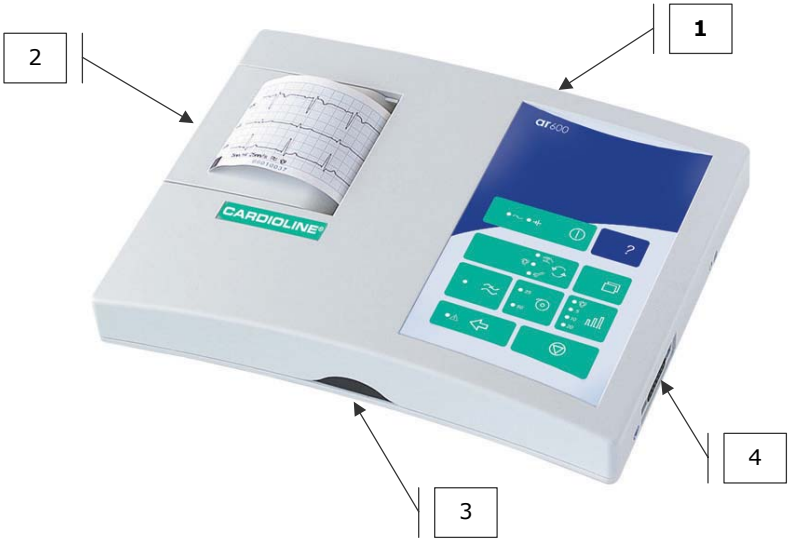
- Always use the device according to the instructions in this manual.
- The device is equipped with a set of standard accessories. For reasons of safety, reliability and conformity with the Medical Devices Directive 93/42/EEC, use only original accessories or accessories approved by the manufacturer.
- The device is equipped with a special long-life thermal print head writing system, which allows maximum writing precision. To avoid frequent and costly replacements and repairs, always use the original paper or paper approved by the manufacturer. The manufacturer does not accept responsibility for any damage to the device or any other effect on it, caused by the use of unsuitable paper.
- Do not subject the device to impact or excessive vibrations.
- Do not allow liquids to penetrate inside the device. If this should accidentally occur, have the functional efficiency of the device tested by a Qualified Assistance Centre before using it again.
- Make sure that the value of the supply voltage corresponds to that indicated on the data plate of the device.
- If you are using the device in connection with others, ensure that: all connections are made by skilled persons; all connections comply with safety regulations; all other devices connected respond likewise to regulations. Non-compliance with regulations can cause physical harm to the patient connected and to the person operating the device. Should it be difficult to obtain the necessary information for assessing the risk of the individual connections, apply directly to the manufacturers concerned or avoid making the connections.
- If other equipment is used, connected directly or indirectly to the patient, check the possible risks caused by the sum of the leakage currents on the body of the patient.
- The device is protected against defibrillation discharges according to standards IEC 601-1-25; to ensure that the signal is restored, use only original electrodes or electrodes responding to IEC and AAMI standards.
- If an electrosurgical scalpel is in use, the patient cable should be disconnected from the device.
- At all events, when defibrillators or high-frequency surgical devices are being used at the same time, it is essential to take the greatest care. If there is any doubt concerning their use, disconnect the ECG patient cable temporarily.
- The device recognizes the impulses generated by a pacemaker and does not interfere with its operation, as prescribed by standards in use at the time of drafting this manual.
- Periodically check the efficiency of all accessories and of the device itself. Use the built-in test function to make a first check of the equipment's efficiency. Contact the Authorized Technical Assistance Center whenever the equipment appears to be malfunctioning.

- To ensure a longer life of your device, it is necessary to have it checked periodically by an Authorized Assistance Center.
- **Caution:** do not use the electrocardiograph for intracardiac applications or for monitoring activities in the operating theatre!
- **Caution:** do not use the device in the presence of anaesthetics or inflammable gases!
- **Caution:** devices for medical applications must be used only by persons who by virtue of training or practical experience are able to ensure maximum safety and effectiveness in operation. Every operator must become familiar with the instrument before using it on a patient.
- **Caution:** the indications obtained using automatic interpreting programs or other diagnostic aids must be passed and countersigned by a qualified medical person!
- **Caution:** use only original "battery chargers" as indicated alongside the connector and in the paragraph "Accessories supplied". The original "battery chargers" ensure the electrical isolation of the patient and the operator, guaranteeing essential conditions of safety. *Do not use* replacement accessories that have not been approved by the manufacturer.
- **Caution:** the device is provided with an IR interface for the transfer of data to other devices. The IR interface must not be masked, even accidentally, as this will adversely affect its capability and its operation, interrupting and preventing the correct flow of data.
- The manufacturer will be responsible for the safety and correct use of the devices only if:
    - modifications and repairs are performed by the manufacturer or by an Authorized Assistance Center;
    - the a.c. power supply of the building responds to current regulations;
    - the device is operated in accordance with user instructions;
    - the accessories used are those approved by the manufacturer.

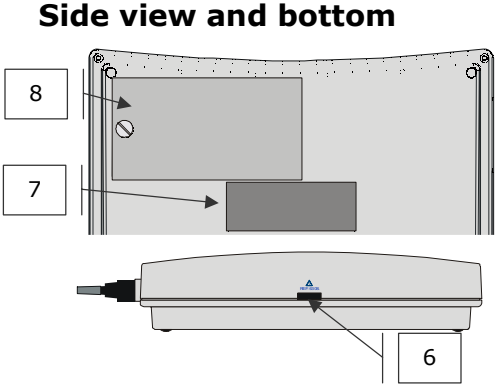
1.3 The electrocardiograph

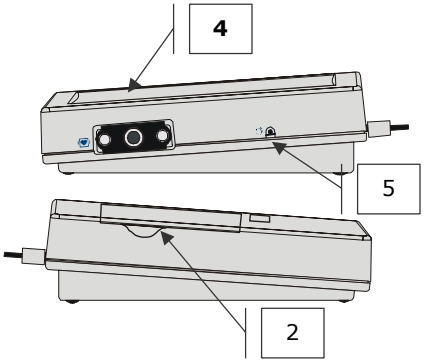
In order to simplify the installation and the use of your electrocardiograph, it is recommended that you become familiar with the component parts and method of operation.

Front view



Side view and bottom





Parts, symbols and commands

1. The keyboard

Function key	Associated LEDs	
On / Off		- LED on: device connected to a.c. power supply; internal batteries charging
		- LED off: batteries charged - LED blinking: charge level of batteries lower than 30% - LED on: internal batteries; the device must be connected to the a.c. supply for recharging.
selection of operating mode		- ECG recording in "manual mode"
		- ECG recording in "automatic mode"
		- "setup mode"; access to configuration menu
		- ECG recording in "PC ECG mode"
Selection of recording sensitivity		- automatic sensitivity: the device optimizes the ratio between n° channels and available space
		- sensitivity 5 mm/mV
		- sensitivity 10 mm/mV
		- sensitivity 20 mm/mV
mains and muscle interference filter		- LED on: filter on
selection of paper speed		- paper speed 25 mm/s
		paper speed 50 mm/s
start selected operating mode		- LED on: electrodes not connected or insufficient contact; saturation
interrupt current operation; stop		

2. Paper compartment cover

3. IR interface

4. Connector for the CF type patient cable protected from defibrillation as indicated by the symbol

5. "Reset" key : allows normal operating conditions to be restored in the event of an error that cannot be managed using the other keys

6. "Battery charger" connector

7. Data plate. In the event of communicating with Authorized Assistance Centers, refer to the data indicated

8. Battery compartment cover

2 Installation and initial preparation

This section describes the operations to be performed prior to using your new **CARDIOLINE® ar600** electrocardiograph. Suggestions are given for "*selecting the installation site*" and "*recommendations for safe use in conformity with current statutory regulations*" are indicated. Also introduced are the operations involved in preparing the electrocardiograph for use, such as "*loading the heat-sensitive paper*", "*power supply; control and management of the internal batteries*", "*switching on and off*", "*setup*".

2.1 Selecting the installation site

The **ar600** electrocardiograph complies with European directives on electromagnetic compatibility. The absence of emissions damaging to radio and telecommunications transmissions is therefore assured, as also is protection from interference emitted by other systems and equipment. Nevertheless, in order to protect your device from other equipment not in conformity with the aforementioned directives:

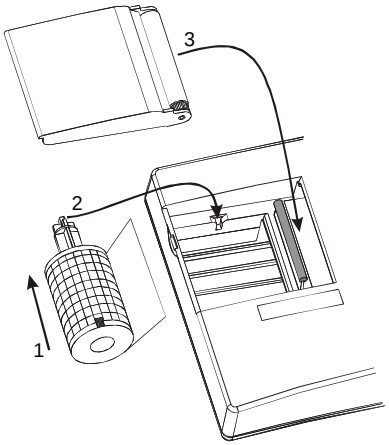
- avoid the use of mobile phones in the vicinity;
- place the electrocardiograph as far as possible from electrical power lines or from sources of static electricity. The ECG signal can in fact be disturbed if the electrocardiograph is situated in proximity to sources of high voltage or electrical lines;
- avoid placing the electrocardiograph close to other diagnostic or therapeutic equipment (e.g. X-ray machines, ultrasound machines, electrically operated beds, etc.) that could be a source of excessive interference and ECG signal distortion;
- if it is impossible to position the electrocardiograph away from other electrical equipment, switch off such equipment when recording an ECG.

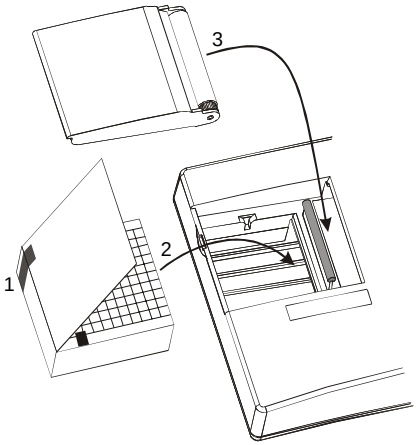
Also, observe the ambient operating conditions when recording ECGs:

- record in a room where the temperature is between 20 and 25 degrees Centigrade. This precaution prevents the patient from feeling cold, which could increase shivering and contribute to muscle tremor;
- Avoid exposing the equipment to extreme temperatures, excessive dust or dirt, and very salty or humid environments; refer to the ambient conditions described in detail under the "*Technical characteristics*" heading.

2.2 Loading the heat-sensitive paper

CARDIOLINE® ar600 is able to reproduce the ECG signal both on heat-sensitive paper in rolls and on heat-sensitive paper in packs. No special setup procedure is required for either. This sections gives the instructions for the correct loading of both types of paper.





If using rolls of paper:

a. Using a coin or similar instrument, open the paper compartment and remove the "roll guide" hub. *If replacing a depleted roll, recover the hub before throwing away the core of the previous roll.*

b. Slot the hub into a new roll of paper (1) and locate in the paper compartment, positioning the pins in the sockets (2). *Ensure that the black mark on the paper is on the lower part of the roll*.

c. Close the cover, positioning the paper between the rubber roller and the casing of the device (3).

If using packs of paper:

a. Using a coin or similar instrument, open the paper compartment and remove the "roll guide" hub. *To avoid accidentally losing the hub, store it in a safe place.*

b. Prepare a new pack (1) and position it in the compartment (2). *Ensure that the black mark on the paper is on the lower part of the pack*.

c. Close the cover, positioning the paper between the rubber roller and the casing of the device (3).

Warning: *use only original heat-sensitive paper or paper approved by the manufacturer. The use of paper that does not respond to the manufacturer's specifications could jeopardize the correct operation of the device.*

2.3 Power supply; control and management of the internal batteries

Your electrocardiograph uses a dual power supply system: a.c. mains and NiMh rechargeable internal batteries.

The rechargeable batteries come as a pack of 4+4 elements housed in the battery compartment on the bottom of the device, and are protected against short circuits.

Caution: *before using the device, it is necessary to go through a complete cycle of recharging of the batteries! However, it is advisable to connect the appliance to the mains during the installation procedures.*

To connect the electrocardiograph to the mains, connect the "battery charger" (provided) to the connector

on the back of the device. The "battery charger" is protected against short circuits by an internal fuse (not replaceable) and against overheating.

Caution: *the battery charger is a class II power supply and does not require earthling of the electrical system.*

Caution: *when the device is connected to the mains, the internal batteries are recharged automatically, even during use.*

To gain maximum benefit from the characteristics of the dual power supply system, follow the indications given below.

Recharging the batteries

The batteries must be recharged when the LED begins to blink, signifying that the reserve charge is lower than 30%.

Connect the electrocardiograph to the mains: LED turns on. Complete recharging of the batteries requires about 14 hours.

The batteries can be recharged in part, or the device can be kept connected permanently to the mains. *For longer life, the batteries should be allowed to run down and recharged completely at least every two months.*

A complete recharge allows the recording of up to 500 complete ECGs (automatic recording mode, 3 channel print format, speed 25 mm/s. When recording with single channel print format, the number is reduced to 250).

If the batteries have completely run down (LED lit), it is still possible to make an ECG recording by connecting the device to the mains.

The average life of the batteries is more than 300 complete discharge/recharge cycles.

Caution: *do not dispose of spent batteries as ordinary refuse or litter. Use only original batteries provide from the manufacturer. The battery lifetime is approximately one year.*

Battery charger: precautions for use

- The "battery charger" can be damaged if dropped, struck or tampered with.
- Do not immerse the "battery charger" in water or other liquids. When using it, do not place it on or near sources of heat.
- Do not damage or tamper with the cables for connection to the mains and to the electrocardiograph.
- Connect the "battery charger" to the electrocardiograph only by means of the connector provided.
- Use the "battery charger" only at the specified mains voltage. If the "battery charger" provided is not compatible with your mains supply, ask the nearest Authorized Assistance Center for a suitable model.

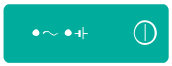
2.4 How to switch on the electrocardiograph

for at least two seconds.

The LEDs corresponding to the settings previously selected will light up: you can proceed.

Caution: *if the LED* ●⊣⊢ *remains alight or blinking, internal power is insufficient and the batteries must therefore be recharged, connecting the device to the mains (see paragraph* "Power supply; ..." *). The batteries are recharged even if the device is in use.*

2.5 How to switch off the electrocardiograph

 .

The LEDs corresponding to the selected settings will extinguish. The memorized ECG, if any, and the settings for the last recording, are stored in the memory.

Caution: *switching off is not enabled 1. during the transmission of an ECG to a PC; 2. during the self-test routine; 3. if "setup" mode is active. In these cases, first stop the device* *and then switch off.*

Auto power off

To preserve the battery charge, the electrocardiograph is provided with an auto power off function that will activate automatically, depending on the amount of power still available and on the operating mode selected. *The procedure is activated only after the current operation has been completed*.

- After 10 min. have elapsed without any key being pressed: reserve power > 30%.

- After 1 min. has elapsed without any key being pressed: reserve power between 15 and 30% (LED ● blinking).
- After 10 sec. have elapsed without any key being pressed: reserve power < 15% (LED ● alight).

If the auto power off function is activated, the current ECG and settings (if applicable), will be stored in memory.

Auto power off is inhibited if:

- a recording is in progress in PC-ECG mode.
- during the self-test routine;
- during "setup".

2.6 Setup of the electrocardiograph

Some of the characteristics of your electrocardiograph can be set according to individual preference and convenience. The characteristics that can be configured are listed in the "*Setup Menu*".

Within the menu, it is possible to activate the self-test function of the device (see paragraph *"Maintenance"*).

How to access the "Setup Menu"

to select "setup mode": LED ● on.

to print the menu and the active setup.

How to change the setup

Accessing the setup menu, a page is printed which shows the list of the available setup options.

The active setup is highlighted by two square brackets **[...]**.

Press the key associated with each option to change the selection.

Selections available

Print format

Setup Option	Status (selections available)	... change selection
☑ No. channels	[1] 2 3	?

Up to three print formats are available: [1] channel per page, [2] channels per page, [3] channels per page. The appendix illustrates examples of recordings in different formats (see "Print formats - examples").

The format selected will be applied to all the recordings in manual and automatic mode.

Automatic calculation of ECG parameters (ECG measurements)

Setup Option	Status (selections available)	... change selection
☑ Calculate parameters	Yes [No]	

The program for automatic measurement of the ECG parameters allows a report of the principal measurements calculated to be obtained at the end of each automatic recording.

Selecting [Yes] the program will be performed automatically at the end of acquisition; selecting [No], no measurements will be calculated.

PC ECG recording mode

Setup Option	Status (selections available)	... change selection
☑ PC ECG	Yes [No]	

The PC ECG function allows real time viewing of the twelve leads on the screen of your Computer using "R.T.E." 4057 (Real Time ECG) software.

Selecting [Yes] it will be possible to select the PC ECG operating mode, from the keyboard, in addition to the traditional automatic and manual modes; selecting [No] this selection will not be possible.

Saving to Personal Computer archive

Setup Option	Status (selections available)	... change selection
☑ PC archive	Yes [No]	

Using the PC Archive function, in association with CARDIOLINE software, a trace recorded and stored in automatic mode can be transferred to a computer.

Selecting [Yes] the action "activate transmission to PC" is associated with the key ; selecting [No] the associated action is "print copy of last recording".

ECG report length

Setup Option	Status (selections available)	... change selection
No. pages auto	[1] 2	

It is possible to select the length of the signal to be represented on paper during automatic recordings, indicating the number of pages to be used.

Two options are available: [1] page per lead or group of leads (if a multi channel format has been selected); [2] pages per lead or group of leads (if a multi channel format has been selected).

The option selected will be applied to all recordings in automatic mode.

Mains frequency

Setup Option	Status (selections available)	... change selection
Mains frequency	[50] 60	

To ensure correct operation of the device, the program must be set to recognize the mains frequency adopted in the area of use.

Two options are available: [50] Hz; [60] Hz.

The option selected will have an effect, both on the battery charging process and on the operation of the filters used to reduce mains interference.

Self-test

Setup Option	Status (selections available)	... change selection
Self-test		

To verify correct operation of the electrocardiograph, the self-test routine can be run by accessing the dedicated menu. For details, see "Maintenance - Self-test".

How to quit the "Setup Menu"

to quit "setup mode". Select a new operating mode to continue.

3 Preparing for an ECG recording

Below are described the operations to be performed prior to recording a resting electrocardiogram with the **CARDIOLINE® ar600** electrocardiograph. In particular, indications are given on "*connecting the patient cable*", "*suitably preparing the patient*", "*applying the electrodes*". Moreover, the necessary procedures for choosing the correct recording parameters, such as "*speed, sensitivity and inserting the filters*", are illustrated.

3.1 Connecting the patient cable

Connect the terminal plug of the patient cable to the connector identified with the symbol , positioned on the right side of the device.

Note: *to avoid breaking the patient cable, remove it from the connector without tugging it, gripping it by the plug.*

Warning: *the device is internally protected against defibrillation discharges; in order to guarantee the resetting of the signal, it is necessary to use protected electrodes. To ensure that safety conditions are respected, use only original accessories.*

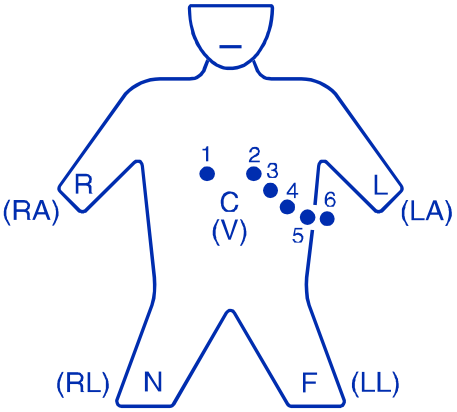
3.2 Preparing the patient and applying the electrodes

A careful preparation of the patient and the correct positioning of the electrodes are at the foundation of an ECG recording of high quality.

- ✓ First, make the patient comfortable, he should be warm and relaxed as much as possible; he should lie on his back on an examination bed or table of adequate size with his arms and hands relaxed along the sides of his body: this will minimize the likelihood of trace interference originating from muscle tremor.
- ✓ Thoroughly clean the skin where the electrodes will be placed with alcohol or ether.
- ✓ Connect each unipolar plug of the patient cable (distinguished by colour coding) to the respective electrodes, observing the *colour-position* relationship indicated below:

Colour	***Symbol***	***Electrode position***
Red	R	right arm
Yellow	L	left arm
Green	F	left leg
Black	N	right leg
White - Red	C1	V1
White - Yellow	C2	V2
White - Green	C3	V3
White - Brown	C4	V4
White - Black	C5	V5
White - Violet	C6	V6

- ✓ Apply a small amount of® electrocardiograph conductive gel on the skin area that will be in contact with the electrode, spreading it carefully (this procedure is not necessary when using disposable electrodes with built-in gel).
- ✓ The following figure shows the standard positioning of the electrodes.



Standard positioning of the electrodes

V1: on the 4th intercostal space along the right parasternal line;

V2: on the 4th intercostal space along the left parasternal line;

V3: on the 5th rib, between V2 and V4;

V4: on the 5th intercostal space, on the left hemiclavicular region;

V5: on the left anterior axillary, at the same level as V4 ;

V6: on the left mid-axillary at the level of V4;

peripheral electrodes: generally a few centimeters above ankles and wrists.

Warning: *make sure that the conductive portions of the electrodes are not touching each other or other metallic parts. In any case,* ***series original electrodes,*** *of silver and silver chloride, are designed and manufactured in order to minimize the likelihood of accidental contact between conductive parts and external metal objects. Ensure that the machine is not affected by disturbances originating from the power supply network (see paragraph* "Initial preparation"*).*

3.3 Selection of recording characteristics: speed, sensitivity, filters

Speed of recording on paper

to select the speed; corresponding LED on. The possible choices are: 25 mm/s and 50 mm/s.

During printing, the speed of the paper flow is indicated by the width of the calibration impulse that precedes each lead and is recorded in the information line

Sensitivity of recording on paper

to select the sensitivity; corresponding LED on. The possible choices are: , 5 mm/mV, 10 mm/mV and 20 mm/mV.

During printing, the sensitivity of recording on paper is indicated by the height of the calibration impulse that precedes each lead and is recorded on the information line

Note: *if you select the sensitivity is set automatically by the device in a way that optimizes the recording over the entire height of the paper. In this case a sensitivity of 2.5 mm/mV may be used. This option is recommended during multi-channel printing. To know how automatic sensitivity is determined, see the paragraph* "Technical Characteristics".

Recording filters

If necessary, it is possible to activate filters capable of improving the legibility of the signal without modifying its morphology. Activation of the filters has an effect on the printed signal. To guarantee a correct and accurate analysis, any automatic interpretation of the trace is performed always and only on the non-filtered ECG signal.

to insert the filters; corresponding LED on. The filters available have been designed to reduce the effect of both mains disturbances and muscle tremors.

The special filter against drift of the isoelectric line (ADF) is always inserted.

During printing, the filters inserted are recorded on the information line.

Caution: *the use of the filters of your ECG is very effective for attenuating disturbances and does not reduce the diagnostic content of the traces. Nevertheless, it is recommended to eliminate the cause of the interference and not just the visible effect on the trace (see paragraphs* "Troubleshooting"*;* "Initial preparation"*)*

4 Recording a resting ECG

4.1 Recording in manual mode

The selected leads are recorded and printed on paper. The signal is recorded in real time, i.e. acquisition and reproduction of the trace are simultaneous.

When operating in manual mode it is possible to establish the duration of registration independently for each group of leads starting from D1 (D1, D2, D3 in multi-channel print format).

- to select "manual mode": LED ● ✍ on.
- to start the recording. If the signal has not yet been initialized the LED ●⚠ lights up momentarily.
- to change the ECG leads being printed during recording
- to interrupt the recording (stop).

Note: *during a manual recording it is possible to alter the recording characteristics: speed, sensitivity, filters.*

Caution: *starting a manual recording cancels the last trace recorded in automatic mode.*

4.2 Recording in automatic mode

All of the ECG leads are simultaneously recorded (10 seconds) The signal printed on paper refers to the same time period and is stored in memory.

An automatic recording allows you to run calculation and analysis programs on the traces available ("ECG measurement" option), to obtain a copy of the recording and to transfer the test to a Computer ("PC archive" option).

- to select "automatic mode": LED ◎ ● on.
- to start the recording If the signal has not yet been initialized the LED ●⚠ lights up momentarily.
- At the end of acquisition, 10 seconds, the LED ◎ ● blinks, indicating that the signal has been completely stored in the memory. It is now possible to disconnect the patient.

to interrupt printing (stop). If the signal is already in memory (LED blinking) it will still be possible to print a copy of the recording.

Automatic calculation of the ECG parameters

The program for automatic measurement of the ECG parameters allows you to obtain a report of the principal measurements calculated at the end of each automatic recording.

- *Start:* automatic at the end of the recording
- *Stop:* automatic at the end of printing the report

The principal items of information in the report are:

- The average ECG complex for the ECG lead with the greatest ST level deviation. The following measurements are indicated by markers on the average ECG complex: onset and offset of the P-wave, QRS and end of the T-wave.
- calculated measurement of the following parameters: QRS duration, PQ-interval, QTc-interval (corrected), ST level deviation, interval RR and heart rate. If any of these parameters are outside of normal limits they are flagged with an asterisk;
- representation of ECG rhythm.

Caution: *if it is not possible to calculate the measurements, a message is reproduced on paper* "Measurements or analysis impossible due to the poor quality of the signal"*. This situation may be due to excessive noise of the ECG trace or to incorrect positioning of the electrodes.*

Copy of an automatic ECG recording

The ECG recording in automatic mode and the respective analysis, if processed automatically, are automatically memorized and can therefore be reproduced on paper an unlimited number of times

to start printing a copy.

to interrupt printing (stop).

If the memory does not contain valid data, the message "*No ECG trace in memory*" is printed.

Note: *memorization of the trace is performed without filtering the signal, notwithstanding the operation of filters during the recording. The parameters may therefore be modified before printing: inserting the filters, speed and sensitivity.*

Caution: *each new acquisition cancels the ECG trace previously stored in the memory!*

Saving an automatic ECG recording to archive on a Personal Computer ☑

Your electrocardiograph is capable of transferring the stored ECG test to a Personal Computer equipped with CARDIOLINE software. For details on the use of the application software, consult the specific manual.

- Place the electrocardiograph in position with respect to the infrared adapter previously connected to the PC.
- to start the transfer.
- to interrupt the transfer before the end.

Caution: *to assist correct data transmission, position the IR adapter for PC at a distance of no more than one meter. Avoid placing objects between the two interfaces.*

4.3 Recording in "PC ECG" mode ☑

The twelve ECG leads are displayed in real time on your Computer screen where, thanks to the CARDIOLINE software, it is possible to perform all the ECG recording operations. Your **ar600** therefore becomes an acquisition system based on a PC. For details on the use of the application software, consult the specific manual.

- Place the electrocardiograph in position with respect to the infrared adapter previously connected to the PC.
- to select "PC ECG mode": LEDs lit.
- to start transmission. During transmission the LEDs blink.
- to end transmission.

Caution: *to assist correct data transmission, position the IR adapter for PC at a distance of no more than one meter. Avoid placing objects between the two interfaces.*

4.4 Defibrillation

In the case of defibrillation, the LED lights up. Within 10 seconds of the discharge, the signal is automatically reset (if the paper reproduction of the

signal was activated in manual mode)

Always remember to avoid direct contact between the electrodes of the defibrillator and those of the electrocardiograph. The approved electrodes supplied as original equipment with your electrocardiograph were developed so as to minimize the risk in case of accidental contact.

5 Management and control of the functions of the electrocardiograph

5.1 Disconnected electrodes, potential presence of defibrillation

Saturation events are controlled and monitored by your electrocardiograph. The operation of the electrocardiograph depends on the current operating phase.

Stop phase

- ✓ *LED* ●⚠ *blinking:* critical electrodes contact. It is possible to proceed with the recording; the "critical" electrodes are indicated on the print report in the information line (for example "⚠ L 1 " indicates the critical nature of the left arm electrode and of the electrode C1).
- ✓ *LED* ●⚠ *on*: electrodes disconnected (saturation). It is not possible to start an automatic recording. A manual recording may be started; the "disconnected" electrodes are indicated on the print report in the information line and a flat signal will be reproduced on paper corresponding to the lead that cannot be acquired due to the absence of an electrode (for example "⚠ L 1" indicates the saturation of the left arm electrode and of the electrode C1).

Manual recording phase

The event is indicated as in the stop phase. When normal conditions have been restored, the signal is centred.

Automatic recording phase

If the event is detected during acquisition (10s), the ECG is stopped and automatically returns to the stop phase If the signal is already in the memory, printing continues without interruptions. The indication of the event is the same as in all the other phases.

Defibrillation

The LED lights up ●⚠. See paragraph "*Defibrillation*".

5.2 Batteries low on energy or no charge

The batteries must be recharged when the LED ●⊣⊢ begins to blink: the reserve charge is lower than 30%.

Follow the indications supplied in the paragraph "*Installation and initial preparation*".

5.3 Print system control. Out of paper

The correct closure of the paper cover is monitored and depletion of the thermal paper generates a warning signal. During a recording, printing is automatically blocked and the LEDs blink for 5 seconds.

5.4 Status messages & errors indication: description and related event

Below are listed the various error messages printed on paper and the behavior of the LEDs in case of unusual events. Each message and LED is correlated to a specific condition or operating phase

Messages

Message	***Status / event description***
Measurements or analysis impossible due to the poor quality of the signal	It is not possible to perform automatic calculation of the ECG measurements because the signal is too noisy
No ECG trace in memory	Impossible to obtain copy of the last recording

LEDS

Description	***Status / event description***
● ⊣⊢ blinking	Batteries low on energy
● ⊣⊢ alight	No battery charge
● ⚠ alight	Disconnected electrodes or potential defibrillation
● ⚠ blinking	- Critical electrodes - Standby for signal centering prior to start printing
● blinking	The signal recorded in automatic mode has been memorized
● ● ● blinking	Function selected active
	Out of paper or paper cover open

5.5 Troubleshooting

The following table summarizes problems which may occasionally occur and their causes

Problem	***Cause***
Drift of the isoelectric line	- Use of electrodes other than originals - Use of electrodes in saturation - Insufficient electrode/skin contact - Electrode surface dirty - Patient moving
Interferences of the electrical supply	- Voltage generator too close; presence of other clinical instruments (e.g. X-rays, Ultrasound etc.) - Patient in contact with metallic parts or with other persons
Muscle tremor	- Patient not relaxed - Loose or improper Peripheral electrodes
Improper paper flow	- End of paper roll - Paper roll incorrectly positioned - Use of improper paper
Impossible to perform ECG analysis	• Signal too unstable or noisy
Not possible to copy ECG	• Recording interrupted before 10 seconds
Excessive noise on the ECG	- defective patient cable - defective electrodes

6 Maintenance

6.1 Self-test

Periodically carry out the self-test procedure which permits a functional check of the writing system, electronic parts, of the keys and of the LEDs.

In the event of error messages, contact the **CARDIOLINE®** Authorized Assistance Center, which will do whatever is necessary to eliminate the causes of the malfunction.

Access to the self-test menu is accomplished from the "setup mode". Before starting the self-test procedure, ensure that there is paper in the machine.

- to select "setup mode": LED on.
- to print the menu.
- to access the self-test menu.
- start LED test: all the LEDs light up in sequence.
- start keyboard test: follow the printed instructions.
- start printer test: two triangular waves are printed, the characters available in memory, signals with different speeds and sensitivities. Anomalies of the printing system are detectable by non-continuous lines.
- start memory test: a message concerning the memory status is printed.
- print ECG information chart. Notify the information listed in all communications with the Assistance Centers.
- to quit the menu.

6.2 Replacement of the heat-sensitive paper

When the heat-sensitive paper is used up, the device stops and any attempt to start recording is blocked (see paragraph "*Print system control. Out of paper*".)

To replace the paper, proceed as indicated in the paragraph "*Installation and initial preparation*".

6.3 How to clean the device and the electrodes

To clean the device, use a cloth dampened with water or denatured ethyl alcohol. Do not use other chemical products or household detergents.

For the electrodes: remove the electrodes from the patient cable and wash under running water. Do not scratch the electrodes and do not wet the leads box and the patient socket.

Note: *the device cannot be sterilized! The electrodes can be sterilized with oxide of ethylene.*

6.4 How to replace the batteries

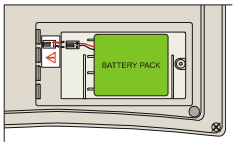
If the operation time in battery mode is considerably reduced or if it's no more possible to operate the recorder in battery mode, the batteries must be replaced.

The battery lifetime is approximately one year.

Attention: *be sure to use original batteries containing protection circuit.*

Attention*: When removing or inserting the batteries from the recorder make sure that the recorder is turned off and the A.C. power cord is disconnected from the mains, otherwise the patient and the operator may be subjected to an electrical shock.*

1. Open the battery compartment.



2. Remove the batteries taking off the connector, please remember to take note of connection polarity (red+, black-).
3. Insert the new batteries and reconnect the connector observing the polarity (red+, black-).
4. Close the batteries compartment.
5. Before using the device, refer to the recharge instruction (see § "Recharging the batteries").

Attention*: the non-respect of the batteries connection polarity may cause serious damages to the device as well as the warranty validity failure.*
Attention: *do not dispose of spent batteries as ordinary refuse or litter. Use only original batteries provide from the manufacturer.*

***Note**: the removal of the battery pack doesn't cause the data loss.*

6.5 Periodic checks

To ensure correct and long-lasting operation of the device, it is necessary to have an Authorized Assistance Center perform the following checks

- ✓ paper drive speed calibration: every year;
- ✓ cleaning of the paper compartment, the paper present sensor, and the writing system: every year;
- ✓ checking all the cables and connectors: every year by means of an ECG simulator;
- ✓ general check on functional efficiency of the device and leakage current: every 2 years.

Technical information

et medical devices SpA will supply circuit diagrams, a list of components, and information needed to enable the repair of user-serviceable parts, when requested by qualified persons.

7 Technical Specifications

Service power supply	AC mains with external power supply 230V±10% 50/60 Hz.; available also: 115V±10% 50/60 Hz; device with power supply specified class II (second) REF type: 6308
Maximum current	100 mA at 117 V ~ ±10% 50 mA at 230 V ~ ±10%
Mains protection	Fuse: T 0.5 A
Internal power source	Set of rechargeable NiMH batteries 8x1.2 Vdc; 1500 mAh
Battery protection	PolySwitch 1.5 A - 40 °C in ambient conditions
Internal power supply protection	Pico fuse SHF SLO-BLO T 2 A Littelfuse
Applied part	CF type
Defibrillation protection	Internal
Input dynamics	± 300 mV @ 0 Hz.± 5 mV in pass band
Input impedance	> 100 MΩ on each electrode
Common mode rejection	> 100 dB
Frequency response	0.05 ÷ 150 Hz (-3dB) without filters
Time constant	3.3 s
Acquisition	11 bit 1000 samples/s/channel printing and filters 500 samples/s/channel in calculation and filters Resolution 5 μV/bit
ECG leads	12 standard/cabrera leads
ECG memory	10 seconds for each lead in auto isochronous
Recording sensitivity	*manual:* 5 – 10 – 20 mm/mV ± 5% *automatic:* dependent on number of channels being printed
Writing system	Thermal printer, 8 dot/mm Usable print height 50 mm
Print channels	1 (3 optional)
Print format	1 (2, 3 optional)
Paper transport speed	25 - 50 mm/s
Heat-sensitive paper	*rolls:* length 15 m, gridded. *pack of Z-Fold:* length 18 m, page 60x75 mm, gridded.
Filters	*Mains interference:* Modified digital notch filter 50 - 60 Hz *Anti-drift:* digital high-pass 0.5 Hz, linear phase
Serial interface	Infrared
Keyboard	Membrane, with functional keyboard
Interpretation program	*Parameter calculation* (optional)
Type of use	continuous
Operating modes	*manual:* acquisition and printing in real time *automatic:* simultaneous acquisition
Battery Capacity	*Internal battery:* 3 hours in 1 channel mode
Recharging time	*Internal battery:* 14 hours 100%

Housing protection category	IP 20
Ambient conditions: - operation - transport and storage	 *Ambient temperature:* from +10 °C to +40°C *Relative humidity:* from 25% to 95% (without condensation) *Atmospheric pressure:* from 700hPa to 1060 hPa *Ambient temperature:* from -10 °C to +40°C *Relative humidity:* from 10% to 95% (without condensation) *Atmospheric pressure:* from 500 to 1060 hPa
Dimensions	250 x 60 x 185 mm (length x height x depth)
Weight	1000 grams without paper
Conformity to standards	EN 60601-1: 1990 EN 60601-1/A1: 1992 EN 60601-1/A2: 1995 EN 60601-1/A13: 1995 *General standards for safety of electromedical equipment* EN 60601-1-2: 1993 *Standards on electromagnetic compatibility of electromedical equipment* EN 60601-2-25: 1995 *Particular safety standards for electrocardiographs* EN 60601-2-51/Ed.1: 2001 *Particular standards on essential recording and analysis performance safety of single and multichannel electrocardiographs.*

Basic accessories supplied

- patient cable cod. 63050025
- 6 suction cup electrodes cod. 66030163
- 4 peripheral electrodes cod. 63030105
- bottle gel (260 ml) cod.66020002
- 1 roll paper 60mm x 75m cod. 66010037
- frequency count gauge
- user manual cod.

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